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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,296	12/21/2001	Bjorn Dahlback	INL-054DV	4472

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

037,296

Applicant(s)

DAHLBACK et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 10/14/03
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 20-22, 28-29, 31-32 is/are pending in the application.
- Of the above claim(s) 28-29, 32 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 20-22, 31 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 20-22, 28-29, 31-32 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☒ received in Application No. (Series Code/Serial Number) 08/978285
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Claims 20-22, 28-29 and 31-32 are pending.

Applicant's election of Group I in Paper filed 10/14/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The disclosure is objected to because of the following informalities: In the amendment of 6/3/02, inserting related application data at page 1, the status of parent 08/978,285 must be updated.

At page 4, lines 13-14 reference to claim 1 is improper.

Appropriate correction is required.

Claims meet requirements of 35 USC 101 and 112.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-22 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Griffin et al (WO93/01209).

Griffin et al show purified C4BP immobilized on a solid phase, such as a microtitre plate. See pages 5, 51 and 78-79. This is sufficient to anticipate all claims as follows.

1) No structure is recited for the kit of claims 20-22. Thus the examiner considers the coated plate itself, absent any kit packaging, as anticipating. Also what is disclosed at pages 78-

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79 uses other reagents required to perform an assay, such as buffers, Which applicant clearly contemplates as being a further reagent of a kit (spec. page 14).

2) For claim 31 “for purifying” refers to an intended use. The coated microtitre plates of Griffin et al are sufficient to anticipate because, when a sample containing free Protein S (PS) is added to such a microtitre plate (in accord with the instantly disclosed assay schemes), the coated microtitre plates can be considered to “purify” the free PS that is in the sample by virtue of binding the free PS to the plate.

3) The compositions of Griffin et al that utilize the entire C4BP anticipate, due to “comprising” nature of instant claims. Applicant clearly contemplates use of intact C4BP at spec. page 8.

Alternatively, if weight is given to the “kit” of claims 20-22 as meaning packaging, then note that Griffin et al generally describe kits at pages 36-42, including kits for detecting free PS. The competition assays for free PS, described at page 50, line 3—page 52, line 13 utilize solid phase immobilized C4BP and other reagents, such as buffers, labeled PS peptides, or labeled anti-PS antibodies. Any combination of the se packaged with the solid phase C4BP anticipates.

Alternatively, if one were to package the components required to assay for C4BP (page 52, line 14—page 56, line 5), one would include purified C4BP standards and other reagents, such as buffers. Thus claim 20 would be anticipated.

Claims 20-22 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Hardig et al (JBC, 271, 20861, 1996 – ref C64).

Hardig et al show microtitre plates with immobilized intact C4BP or various alpha/beta chain chimeras of C4BP, including chimeras that contain the extreme N-terminal SCR-module

(SCR-1) of the beta-chain of C4BP. See page 20864, col. 1. As with Griffin et al supra, these anticipate the instant claims.

Further, regarding Hardig et al's use of chimeric polypeptides containing SCR-1 of the beta chain, it is noted that applicant contemplates these as within the scope of instant claims. See spec. page 8.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardig et al in view of Griffin et al.

The teachings of the Hardig et al reference note the fact that intact C4BP or chimeric C4BP function equivalently, when immobilized to a microtitre plate, in the binding of free PS (pages 20864-20866). Griffin et al teach that a microtitre plate with immobilized intact C4BP can be used to assay for free PS (pages 50-52); they also teach components to be used in assays can be packaged in kits (pages 36-42). It hence would have been obvious that kits for assaying for free PS would be provided with immobilized C4BP provided in a chimeric form containing the SCR-1 domain of the C4BP beta-chain. Motivation to use a recombinant form of C4BP, as opposed to an intact C4BP isolated from blood plasma, would have been to avoid the need to obtain large quantities of hard to obtain blood plasma, which would have more important therapeutic uses.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Hillarp et al (JBC, 263, 12759, 1988).

Hillarp et al show an isolated 45 kDa beta-chain of C4BP; applicant contemplates use of such in instant assays and kits (spec. page 4). They also show other reagents, such as radiolabeled human PS (legend of Fig. 4); this reagent could be used in a competitive binding assay for free PS. Hillarp et al thus show all kit components, absent any kit structure.

Linse et al (JBC, 272, 14658, 1997 - ref C94) are noted for teaching aspects of the instant invention. The Swedish priority document supports instant claims; hence Linse et al are not cited.

References lined through on attached form 1449 were not found in the IFW contents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 703-308-3976.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 703-308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Typed 12/17/03 DAS